

**Remarks**

Claims 1-11, 13, 15, 17, 19-23 and 25-30 are pending. Claims 12, 14, 16, 18 and 24 has been cancelled without prejudice. Applicants reserve the right to pursue the subject matter of any of the canceled claims in one or more divisional, continuation, or continuation-in-part applications.

Claims 1-7, 9-11, 13, 15, 17, 19-21 and 28-30 have been amended. Support for the claims can be found in the instant specification and the claims as originally filed thus no new matter has been added.

**Rejection Under §112**

Claims 1-11, 13, 15, 17, 19-23 and 25-30 have been rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the written description requirement. Applicant respectfully disagrees.

The Examiner contends that the instant specification does not sufficiently describe homologs of promoter YMR325W. In order to more clearly point out what the Applicant considers a homolog, independent claims 1, 13 and 21 have been amended. As such, it is clear that homologs of YMR325 promoters are those YMR325 promoter sequences that have incorporated one or more nucleotide substitutions, additions or deletions, however, these sequence alterations do not substantially effect the ability of the promoter sequence to promote transcription of an operatively linked sequence when compared to the wild type YMR325 promoter that does not have any of the one or more nucleotide substitutions, additions or deletions (see, e.g., paragraph 0042, lines 4-12 and paragraph 0043 of the instant specification).

Promoters used in the claimed methods all retain substantially the same indicator function as the wild type YMR325 promoter. One skilled in the art can easily discern if a YMR325 promoter that has one or more sequence alterations is within the scope of the claims by comparing its function to the YMR325 promoter sequence without such alterations. Any of the assays described in the specification or known in the art at the time of filing to assay promoter function can be used. In cases where a complete structure of a species is not disclosed, disclosure of other relevant characteristics, such as structural or other physical and/or chemical, or *functional* characteristics is sufficient evidence that Applicant described the invention adequately. Applicant contends that structural information is provided (e.g., the sequence of the native YMR325 promoter) as well as functional information (e.g., the promoter's indicator properties) such that one skilled in the art could take the provided sequence and alter it as described and then test to see if the described functional property remains.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection under §112.

### **Rejection Under §102**

Claim 1-3, 5-9, 13, 15, 17, 19, 21, 23, 25 and 28-30 have been rejected under 35 U.S.C. §102(e) as being anticipated by US Patent 6,828,092 (hereafter “Dixon”). Applicant respectfully disagrees.

Dixon teaches a method for the identification of agents which modulate sterol biosynthesis comprising contacting host cells with a reporter under the control of acetoacetyl CoA thiolase gene promoter with test compounds. The Examiner contends that the acetoacetyl

CoA thiolase gene promoter is equivalent to a YMR325W homolog. In fact, the Examiner has stated that she interprets the term “homolog” in the claims to be *any* promoter sequence (see page 7, lines 1-2 of the Office Action mailed August 19, 2008). Applicant respectfully disagrees with that characterization for the reasons stated *supra*. Applicant contends that the claims as currently pending encompass YMR325W promoters and homologs that promote transcription substantially as does wild type YMR325W -- not every conceivable promoter in nature.

A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference. In re Paulsen, 30 F.3d 1475, 31 USPQ2d 1671 (Fed. Cir. 1994) Applicant contends that the acetoacetyl CoA thiolase gene promoter used in Dixon is not equivalent to a YMR325W homolog.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection under §102.

### Rejection Under §103

Claims 1-11, 13, 15, 17, 19-23 and 25-30 have been rejected under 35 U.S.C. §103(a) as being anticipated by Dixon in view of International Publication WO 2000/58521 (hereafter “Ashby”), US Patent 7,022,481 (hereafter “Phillips”) and International Publication WO 2001/02550 (hereafter “Contreras”). Applicant respectfully disagrees.

Contreras discloses 484 sequences that were identified as involved in Bax-induced cell death. Applicant is not claiming YMR325W promoter and/or YMR325W homolog sequences, but rather their use in the claimed methods.

There is no appreciation of *any* of the sequences involvement of sterol biosynthesis, much less that any would have the characteristics that would have utility in identifying compounds that affect the pathway and/or monitoring the activity of the pathway. Mere disclosure of a sequence that is similar to the YMR325W promoter does not at all suggests that it would be useful in the claimed methods. Broad, generic disclosures are inadequate to establish obviousness as to a species. *See Ashland Oil*, 776 F.2d at 296-97, 227 U.S.P.Q. at 666-67; *In re Jones*, 958 F.2d 347, 349-50, 21 U.S.P.Q. 2d 1941, 1943 (Fed. Cir. 1992) (disclosure of a genus in a prior art reference does not in itself render a species of that genus obvious).

The test is not whether each difference individually is obvious; rather, it is whether the claimed invention as a whole is obvious. *In re Buehler* (CCPA 1975) 515 F2d 1134, 185 USPQ 781. Applicants contend that the Examiner has shown no reason why one skilled in the art would pick and choose the cited teachings and combine them. Furthermore, the other cited references teach assays using different promoters and/or different read-out assays to be used, however, none teach this promoter used in the claimed methods.

In view of the foregoing, Applicant respectfully requests withdrawal of the rejection under §103.

### Conclusion

It is believed that the claims now pending are in condition for allowance. Early and favorable action by the Examiner is earnestly requested.

**Authorization**

The Commissioner is hereby authorized to charge to deposit account 13-2755 \$130.00 to pay the fee under 37 C.F.R. §1.136(a) for an Extension of Time for one month. Additionally, the Commissioner is hereby authorized to charge any additional fees which may be required for consideration of this Amendment to deposit account 13-2755.

Respectfully submitted,

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